

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Call-in details: Dial **888-557-8511**; Enter Access Code **5222603#**

(Call 202-429-9260 if there are problems accessing the teleconference.)

Monday, January 11, 2010, 1:00 pm – 2:00 pm ET (call to start promptly at 1:00 pm ET)

January 11, 2010 CALL CANCELLED BUT INFO PROVIDED BELOW

Agenda (as of January 8, 2010 – subject to change)

- I. Welcome and Introductions ~~1:00–1:05 pm~~
 - Attendance taken via email (sent to Marcia Howard)
- II. Next Standing Teleconference: January 25, 2010 (unless cancelled)
- III. FDA Data Standards Council/OTC Information (For Your Information *-not all-inclusive*)
 - A. FDA Data Standards Council website – terminology update (January 5, 2010)
 1. UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>
 2. Unit of Measure - Add [hp_M] & [hp_Q] -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml68397.htm>
 3. Updated terminology XML Files (include updated UNII & Units of Measure XML files) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>
 - B. FDA Data Standards Council website – terminology update (January 7, 2010)
 1. UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>
 2. Updated terminology XML File –
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>
 - C. The 2010 Winter/Spring SPL R4 training web conferences
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml55705.htm>

IV. Upcoming SPL Educational Forums/Information (For Your Information)

A. FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

1. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays)
Telephone number: 1-866-775-9435
Participant pass code: 5753366

Please dial-in early as there are a limited number of ports and when they are exhausted, no one else will be able to connect to the conferences.

The 2010 Winter/Spring SPL R4 training web conferences – *NEWLY ADDED*
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

Please visit the SPL Wiki page to access FDA's SPL R4 eBook Training Documents (<http://spl-work-group.wikispaces.com/>)

2. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 558089
Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.

3. **SPL ERDL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)
Telephone number: 866-217-3840
Conference Code: 4286445422
Please email sub-team leader Michael Fahmy if you want to get the email information (michael.fahmy@bms.com).

4. **SPL Generics Sub-team calls:** First Tuesdays of each month at 1:00 pm ET (unless cancelled)
Telephone number: 866-618-6746 (toll-free)
201-527-2133 (international/caller paid)
Access Code: 8957842
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).

B. Other training opportunities???

V. Update

~~1:05–1:20 pm~~

- A. Delisting Issue – *ER/DL sub-team examined pros and cons of alternate solutions for discussion with FDA. FDA is having internal talks and will make decision in future.*
- B. Requesting UNII for Simethicone – *Information provided by interested SPL OTC sub-team members has been forwarded to FDA which will now have to determine how best to proceed.*
- C. Import Issues – *Email information for the companies who completed the original online survey regarding import issues should be sent to Marcia Howard (mhoward@chpa-info.org) if willing to complete follow-up survey.*

VI. Open Discussion by Sub-team Members

~~1:20–1:50 pm~~

SPL OTC sub-team members should contact Marcia Howard if there are topics or issues to be added to the next call agenda.

VII. Other

~~1:50–2:00 pm~~

MDH/01-06-10

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